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Hebenton, Joanne; Scott, Helen; Seenan, Chris; Davie-Smith, Fiona

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The relationship between models of care and key rehabilitation milestones following unilateral trans-tibial amputation: a national cross-sectional study

Article Type: Original Research

Corresponding Author: Joanne Hebenton ^a, joanne.hebenton@ggc.scot.nhs.uk

Co-authors: Helen Scott ^a, helen.scott@ggc.scot.nhs.uk, Dr Chris Seenan ^b,
chris.seenan@gcu.ac.uk, Dr Fiona Davie-Smith ^a, f.smith6@nhs.net

^a, WestMARC, Queen Elizabeth University Hospital, 1345 Govan Road, Glasgow, G51 4TF

^b, Govan Mbeki Building, Glasgow Caledonian University, Cowcaddens Road, Glasgow, G4 0BA

Objectives:

Identify different models of care (MOC) post Trans-Tibial Amputation (TTA) and relate these to achievement of rehabilitation milestones.

Design

Retrospective analysis of rehabilitation milestone data and a survey of MOC in ten vascular centres.

Setting

NHS Scotland Vascular Centres.

Participants

All unilateral TTA between January 2011 and December 2014 (n=643).

Main outcome measures

The time to achieve the rehabilitation milestones: compression therapy, early walking aid, casting for a prosthetic limb, prosthetic delivery, in-patient discharge and final discharge from rehabilitation. MOC were scored according to seven key aspects of service provision.

Results

Mean age of the cohort was 66.7 (\pm 12.5) years, 75.9% males and 62.8% had peripheral arterial disease with diabetes. Mean days to achieve rehabilitation milestones varied across centres: compression therapy (11.9 (\pm 24.9)); early walking aid (27.6 (\pm 36.4)); prosthetic casting 60.2 (\pm 57.5); prosthetic delivery 73.8 (\pm 59.8), in-patient discharge 67.6 (\pm 54.8) and final discharge from rehabilitation 166.1 (\pm 100.6). Only two centres included all seven key aspects of service provision within their MOC. Vascular centres who achieved the optimal MOC also achieved their rehabilitation milestones the quickest.

Conclusions

This study demonstrated a positive association between optimal MOC and early achievement of rehabilitation milestones post TTA. Key aspects of service provision associated with a quicker time to achieve rehabilitation milestones included: use of a post-operative rigid dressing; specialist physiotherapy input in the early post-operative period; daily in-patient gym sessions and in-patient prosthetic provision. This study is the first to document the MOC following TTA relating these to the achievement of rehabilitation milestones.

Contribution of the paper

- This paper provides the first comprehensive identification and exploration of TTA models of care in Scotland.
- Key aspects of service provision associated with a quicker time to achieve rehabilitation milestones included: use of a post-operative rigid dressing; specialist

physiotherapy input in the early post-operative period; daily in-patient gym sessions and in-patient prosthetic provision.

Keywords: Trans-Tibial, Amputation; models of care; rehabilitation milestones; prosthetics; service design

Introduction

Approximately 800 lower limb amputations are performed in Scotland each year, 85% of these are as a result of peripheral arterial disease (PAD) in the presence or absence of diabetes (DM) (1). PAD and DM affects 2.7 million and 4.5 million people in the UK respectively (2–4). This population is predominantly elderly, have significant co-morbid disease, are at increased risk of contralateral limb amputation and subsequently have a higher mortality rate (5,6). Mortality rates after major lower limb amputation for PAD with or without diabetes are as high as 44-48% at one year and 70-77% at 5 years (7,8). Therefore, it is critical that post-operative rehabilitation is optimal, and not prolonged, in order to maximise quality of life.

The primary focus of rehabilitation post-amputation is the recovery of functional independence, and a return to pre-amputation activity, which is more achievable if fitted with a prosthetic limb. Furthermore, this is more realistic following a trans-tibial amputation (TTA) compared to a more proximal trans-femoral amputation (TFA); as the loss of the knee joint greatly increases the physical and cognitive effort required. The Scottish Physiotherapy Amputee Research Group (SPARG) data has demonstrated that approximately 70% of

patients with TTA are fitted with a prosthetic limb, compared to 30% of those with a TFA (Accessed 19.11.18 <https://bacpar.csp.org.uk/publications/sparg-report-2015>).

Prosthetic rehabilitation begins immediately after surgery, includes compression therapy and re-education of gait using an Early Walking Aid (EWA) (9). Compression therapy in an ideal setting would start with a post-op rigid dressing applied in theatre. The next line of compression is a shrinker sock routinely applied from day 5 onwards (10). Initial physiotherapy rehabilitation seeks to reduce the incidence of post-operative complications whilst also promoting early mobility with an early walking aid and provision of a prosthetic limb (11,12). The Pneumatic Post Amputation Mobility Aid (PPAM Aid) is the most commonly used EWA following unilateral TTA (13). Early gait training is associated with satisfaction and daily usage of a prosthetic limb (14), and use of a prosthesis is associated with reduced mortality rates (15) and increased independence and quality of life (11,12,14–16).

Physiotherapy intervention following amputation is determined by the model of care (MOC) in each vascular centre. There is a paucity of published literature defining the “gold standard” model of care for patients undergoing TTA, however variations in MOC have been identified across the UK (17). SPARG identified large variations in MOC for those undergoing rehabilitation after amputation in Scotland (1). Intensive in-patient rehabilitation has been shown to be associated with improved outcomes in the USA (18,19) and in the UK Turney et al.(2001) found that ‘vigorous inpatient rehabilitation’ was associated with ‘mobility success’ at the end of rehabilitation(20). Despite this evidence, there is no current consensus regarding optimal MOC following amputation and current guidelines do not make recommendations

regarding the timing and type of rehabilitation (9). The Scottish Rehabilitation Engineering Technology Group (ScotRET) benchmarked amputation rehabilitation services across Scotland and from this identified the seven key aspects of service provision (21). The aim of this study is to identify the different models of care post TTA in Scotland and explore how aspects of these models of care relate to the achievement of rehabilitation milestones. As those with a TTA are more likely to limb fit and therefore achieve rehabilitation milestones, this study will focus solely on this level of amputation.

Methods

This study was conducted in two phases; Phase 1 was a retrospective analysis of quantitative data collected from the SPARG database. SPARG carries out a national audit of routinely collected anonymised data on every person in Scotland who undergoes a major lower limb amputation. Data includes information relating to aetiology, co-morbidities, timing of rehabilitation, key outcome measures and final outcome regarding limb-fitting and mobility; the centre where the amputation was performed is also gathered. To reduce variables within the cohort and with the aim of providing the most robust conclusions from the data, all participants (≥ 18 years old) who underwent a unilateral TTA between 1st January 2011 and 31st December 2014 due to PAD and diabetes were included. Only the vascular centres with more than 20 unilateral TTA who were limb fitted were included (Fig 1). Due to increased variability within the sample and with the aim of providing the most robust conclusions from the data, all participants with aetiologies other than PAD and diabetes were excluded.

Figure 1 Near Here

The data pertaining to the timing of achieving the six rehabilitation milestones were examined, including the number of days to: compression therapy, EWA, casting for a

prosthetic limb, prosthetic delivery in-patient discharge and final discharge from rehabilitation. The cohort was categorised by the vascular centre where they underwent their TTA.

Phase 2 was a survey of the MOC in the ten vascular centres in Scotland. Each MOC was scored according to the key aspects of service provision, defined by the benchmarking report (21). These seven aspects were: immediate post-op rigid dressing; specialist physiotherapy assessment in first 14 days post TTA; daily in-patient gym session; in-patient gym session more than 1 hour; prosthetic centre on site as in-patient; prosthetic provision i.e. cast, fit & delivery as in-patient; specialist physiotherapy out patient service. Centres were given one point for each aspect of service provision that was included in their MOC, the maximum each centre could achieve was seven points.

The final part of the study was to explore the relationship between the achievement of the rehabilitation milestones and the MOC scores. Descriptive analysis was performed using SPSS version 22 (22). As data were normally distributed, parametric statistics were used and data presented as Mean and SD. The data were grouped according to vascular centre. Independent t-tests and Chi-Squared tests were used to identify any differences between scale and categorical descriptive variables. A one-way analysis of variance (ANOVA) was performed with Tukey post hoc tests to explore any differences in time to achieve the rehabilitation milestones between the vascular centres. Statistical significance was set at $p < 0.05$ and confidence intervals of 95% or more were assumed.

Results

From the SPARG data-base, there were 643 patients who underwent a unilateral TTA between 2011-2014 and were fitted with a prosthetic limb. The mean age of this cohort was 66.7 (\pm 12.5) years old; although this varied from 62.4 years in Centre 9 to 70.1 years in Centre 2 ($p=0.046$). There was a significant difference in age between aetiologies as those with PAD were approximately 4.7 years older than those with PAD and DM ($p<0.001$). The majority of the cohort was male (75.9%) and this ratio was similar across all the centres ($p=0.451$). There was a significant difference in aetiology according to gender with more males having PAD and DM than females ($p=0.002$). Although the entire cohort had their TTA due to PAD, more than half also had a diagnosis of diabetes (62.8%), with fewer in Centre 4 (52.2%) and more in Centre 3 (78.8%) ($p=0.233$) (Table 1).

There was a statistically significant difference between the centres for all six milestones (Table 2). Centre 6 had the shortest time to commence compression therapy and this was statistically significantly quicker than Centres 1 and 2 ($p<0.001$). Centre 6 also had the shortest time to commence EWA use and this was statistically significantly shorter than centres 2 and 9 ($p<0.001$) (Figure 2).

Centre 6 also had the shortest time to casting for a prosthetic limb and this was significantly quicker than Centre 2 ($p<0.011$). Centre 6 also had the fastest time to delivery of the prosthesis and this was significantly faster than centres 2 and 9 ($p<0.001$ and $p=0.049$ respectively) (Figure 3).

Centre 10 had the shortest In-patient stay after TTA and this was significantly quicker than Centres 1 ($p<0.001$), 2 ($p=0.010$), 3 ($p<0.001$), 4 ($p<0.001$), 6 ($p=0.033$) and 7 ($p<0.011$). Centre

6 had the shortest time to final discharge from rehabilitation, and this was significantly faster than Centres 2 ($p<0.001$), 5 ($p=0.007$), 7 ($p<0.001$), 8 ($p=0.027$) and 9 ($p<0.001$) (Figure 4).

From the analysis of the MOC data, only Vascular Centres 3 and 6 included all seven key aspects of service provision, while Centre 1 included less than half of the key aspects (Figure 5).

Discussion:

This study identified the different MOC following unilateral TTA in Scotland for the first time. It is also the first study to compare vascular centres by the time taken to achieve rehabilitation milestones. Furthermore, it has shown that there is an association between the MOC and the time taken to achieve these rehabilitation milestones. MOC in this study were based upon the benchmarking of seven key aspects of service provision.

The first of these aspects is the use of compression therapy to help reduce oedema and accelerate rehabilitation. Current evidence suggests that this should be started in theatre at time of TTA with a post-op rigid dressing (10,23). Although centres 3, 6 and 7 stated they used post-op rigid dressings routinely, centre 6 commenced rigid dressings immediately post-op (0.5 days \pm 3.1). Despite centres 3 and 7 stating they used rigid dressings routinely, the retrospective data analysis did not support this as compression therapy started later (6.3 and 2 days post-op respectively). Following on from the use of their rigid dressings, centre 6 was also the quickest to start EWA use (14 days \pm 9.1).

The EWA of choice was the Pneumatic Post Amputation Mobility (PPAM) aid, which applies compression to the residuum, this in combination with the effect of mobilisation on the

cardiovascular system, increases circulation, reduces oedema and promotes wound healing; this is essential to allow early prosthetic fitting (23,24). All ten centres used the PPAM aid routinely, however starting PPAM aid use varied from 14 days to 49.3 days post TTA (Table 2). Gym sessions will have a direct impact on timing, duration and frequency of PPAM aid use as it is a physiotherapy device. Centres 7 and 8 have the longest gym sessions and provide these 5 days per week. Interestingly although centre 8 has a longer time to commence compression therapy (9.2 days) and does not use rigid dressings it has one of the fastest times to EWA use (14.9 days) second only to centre 6. The specialist physiotherapists at centres 7 and 8 are the only teams whose remit is solely vascular, allowing them to deliver longer gym sessions within the first 14 days which promotes early mobility.

Current literature supports comprehensive and intensive in-patient rehabilitation post amputation (19,25). In these studies, optimal outcomes were associated with provision of a prosthetic limb and completing rehabilitation as an in-patient. In this study, the mean length of in-patient stay varied from 32.7 days to 103.9 days (centres 10 and 4 respectively). Interestingly centre 10 who had the shortest in-patient stay also had the longest time to final discharge from rehabilitation (210.9 days). Centre 10 also started EWA use after the patient was discharged home from hospital (33.4 days) and there was no prosthetic service on site.

A delay in provision of a prosthetic limb (>60 days post TTA) even after controlling for demographic, socioeconomic and amputation-related characteristics has been shown to be associated with dissatisfaction with the device and therefore a reduction in its use (26). Although centres 6, 7 and 8 have the quickest times to casting and delivery of the prosthetic limb, centre 8 does not have a prosthetic service on site; as such it takes the longest of these

three for casting and delivery. Conversely, centre 2 is the slowest in achieving all rehabilitation milestones and has a prosthetic service on site. The delayed time for casting and delivery in centre 2 may be attributed to the delay in starting compression therapy and EWA use as there is a known link between mobility with an EWA and reduction in stump volume in preparation for casting of the prosthetic limb (10). Centre 2 also has a physiotherapy team that is not designated to vascular, and despite having daily gym sessions these are not more than one hour in length. The demographics of centre 2's cohort are not dissimilar to others in terms of gender and aetiology however they were the oldest cohort of all the centres (70.1 years) which may be a factor in the increased length of time taken to achieve milestones.

The time taken to reach rehabilitation milestones is important in the amputee population as many will have a shortened life expectancy, due to their high mortality rate and additional comorbidities (7,8). Increased mortality is also associated with delayed decision making prior to amputation and not being fitted with a prosthetic limb following amputation (15,16,27). Achieving the key rehabilitation milestones in the shortest time may reduce mortality and improve usage of the prosthesis which may impact positively on the quality of life in this population. Centre 6, who provided all seven key aspects, reached key rehabilitation milestones in fewer days in five of the six milestones. This suggests that the MOC is associated with time taken to achieve rehabilitation milestones following a unilateral TTA. However, centre 3 also had an optimum MOC score according to the seven aspects and despite this did not achieve the rehabilitation milestones more quickly. The reason for this may be that their patients had greater incidence of diabetes than any other centre (78.8%) which has a known impact on healing time and complications post-operatively (28).

A strength of the current study is its large retrospective cohort, which was a consecutive sample of all those with a TTA who were limb-fitted in Scotland; therefore, increasing the external validity of the study and the ability to generalise the results to other populations. This data set is also the most up to date, intact data set for the Vascular centres being discussed. One of the observations of this study is the variance in numbers across the vascular centres, however the consecutive sampling of the patients aids with reducing the skewness of the data. Centres 7 and 8 had the highest number of patients (n=93 and n=161) whereas centre 5 had the lowest number (n=25). With varying numbers in the ten centres there may be a large variation in the experience of the physiotherapy staff and the understanding of how to best achieve rehabilitation milestones in the quickest time possible.

Conclusions

The aim of this study was to identify the different models of care following unilateral TTA in Scotland and explore how they relate to the achievement of rehabilitation milestones. Models of care varied across the vascular centres in Scotland and there was significant disparity in the timing of rehabilitation milestone achievements following unilateral TTA. The ability to achieve a short time to cast and delivery of a prosthetic limb appears to be influenced, not only by the presence of a prosthetic service on site but also by commencing compression therapy and EWA use in a timely manner. The latter is only possible with a specialist physiotherapist and access to gym sessions on a frequent basis. Given the high mortality rate of the dysvascular lower limb population it is imperative that these services are available to provide the most effective rehabilitation in the shortest time.

Conflict of interest

There are no conflicts of interest.

Ethical Approval

Ethical approval for the study was obtained from the National Institute for Social Care and Heath Research Academic Health Science Research Ethics Service (Reference: 14/WA/1025).

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| Amputations in Scotland 2011-2014 (n=3163 from 22 centres, including 10 vascular centres) | |
|--|--|
| Inclusion <ul style="list-style-type: none"> • Transtibial (n=1713) • Unilateral (n=1373) • <18 years old (n=1359) • Aetiology PAD+/-diabetes (n= 1162) • Amputation at one of 10 vascular centres (n=1106) • limb fitted (n= 701) • No further surgery (n= 644) • Missing data (n=1) | Exclusion <ul style="list-style-type: none"> • Non-transtibial (n=1450) • Bilateral (n=340) • <18 years old (n=14) • Aetiology not PAD+/-diabetes (n= 197) • Amputation out with the 10 vascular centres (n=56) • Non limb fitted (n= 405) • Revised to trans femoral level (n= 70) • Missing data (n=1) |
| 643 data sets included in analysis | |

Figure 1: Inclusion and exclusion criteria for Phase 1.

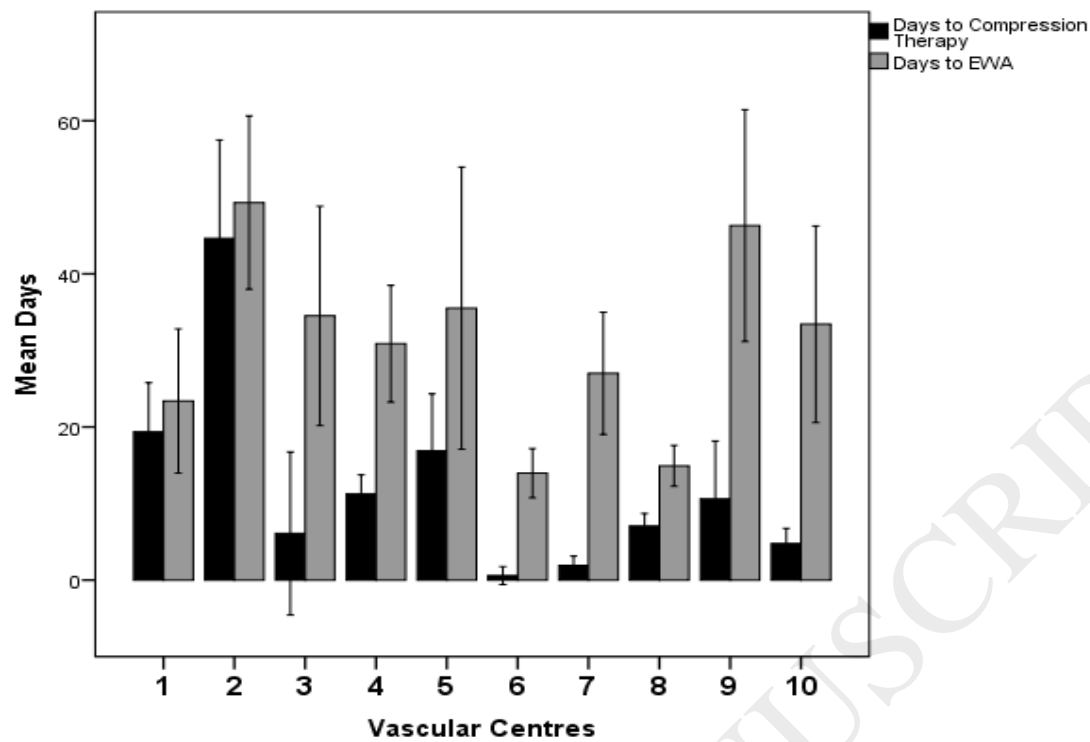


Figure 2: Days to Compression and EWA use across the Vascular Centres

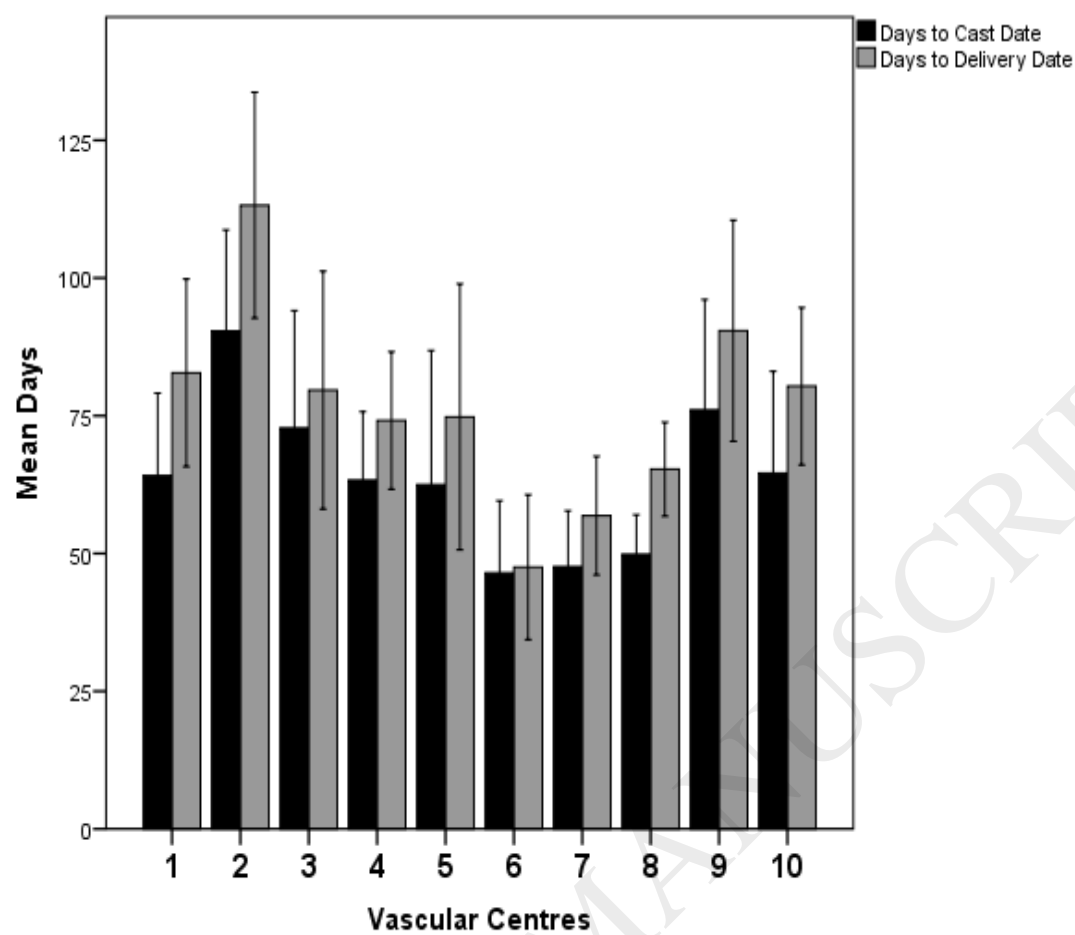


Figure 3: Mean Days to Cast and Delivery of prosthesis across the Vascular Centres

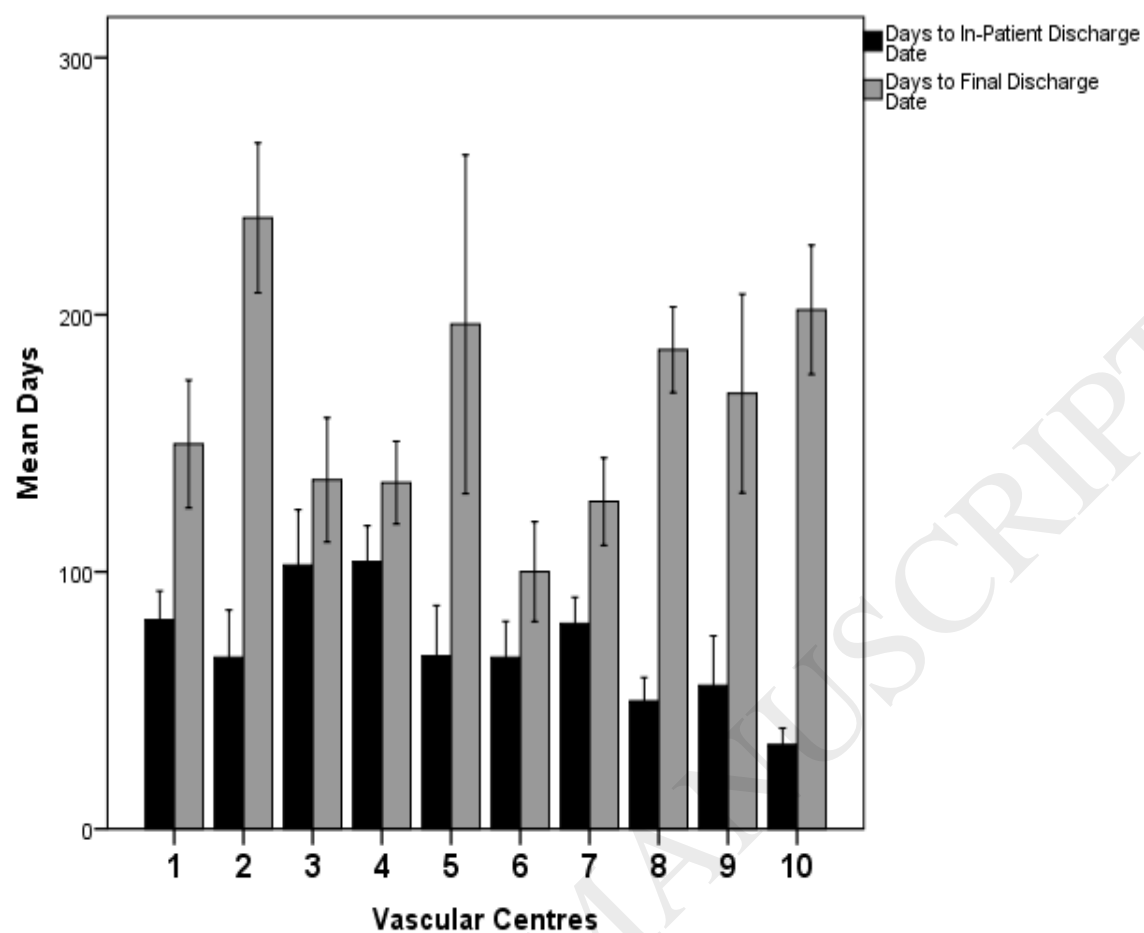


Figure 4: Mean Days to In-Patient and Final Discharge from Rehabilitation across the Vascular Centres

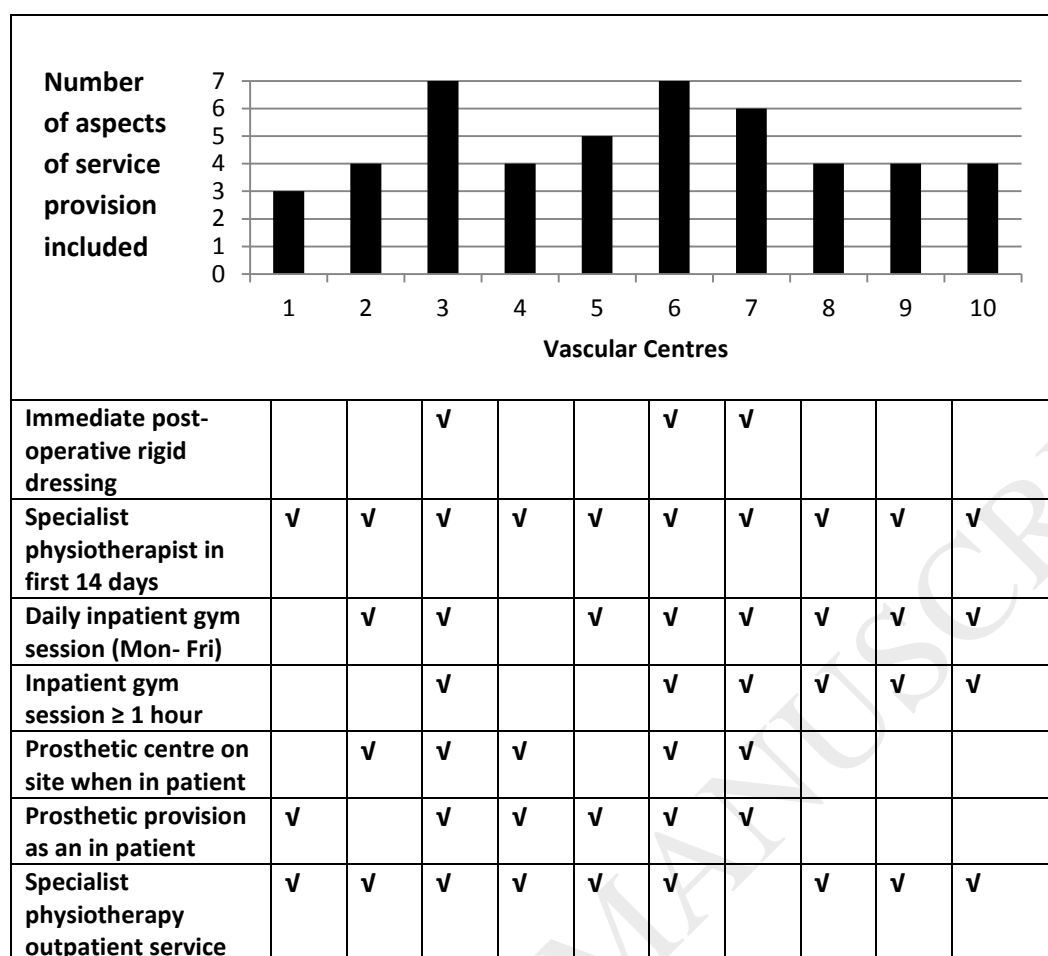


Figure 5: Aspects of service provision by vascular centre

Table 1: Participant demographics across all Vascular Centres

| | Vascular Centres | | | | | | | | | | | |
|-----------------------|------------------|-----------------|-----------------|-----------------|-----------------|---------------|-----------------|-----------------|------------------|----------------|-----------------|---------|
| | All (n=643) | 1 (n=56) | 2 (n=53) | 3 (n=32) | 4 (n=66) | 5 (n=25) | 6 (n=37) | 7 (n=93) | 8 (n=162) | 9 (n=36) | 10 (n=72) | p value |
| Mean Age (SD) | 66.7 (12.5) | 65.6 (12.5) | 70.1 (12) | 65.6 (11.6) | 66.3 (14.2) | 67.7 (12) | 68 (12.3) | 70 (13.2) | 65.7 (11.6) | 62.4 (13.8) | 64.9 (11.4) | 0.046 |
| Males % (n) | 75.9% (n=488) | 78% (n=46) | 67.9% (n=36) | 66.6% (n=22) | 85.1% (n=57) | 72% (n=18) | 75.7% (n=28) | 79.8% (n=75) | 73.3% (n=121) | 73% (n=27) | 79.5% (n=58) | 0.451 |
| Female % (n) | 24.1% (n=155) | 22% (n=13) | 32.1% (n=17) | 33.4% (n=11) | 14.9% (n=10) | 28% (n=7) | 24.3% (n=9) | 20.2% (n=19) | 26.7% (n=44) | 27% (n=10) | 20.5% (n=15) | |
| PAD % (n) | 37.2% (n=239) | 32.2% (n=19) | 35.8% (n=19) | 21.2% (n=7) | 47.8% (n=32) | 28% (n=7) | 37.9% (n=14) | 42.6% (n=40) | 37% (n=61) | 27% (n=10) | 41% (n=30) | 0.233 |
| PAD + DM % (n) | 62.8% (n=404) | 67.8% (n=40) | 64.2% (n=34) | 78.8% (n=26) | 52.2% (n=35) | 72% (n=18) | 62.1% (n=23) | 57.4% (n=54) | 63% (n=104) | 73% (n=27) | 59% (n=43) | |

Table 2: Mean (SD) days to achieve rehabilitation milestones in all Vascular Centres (*p* values represent findings from One-Way ANOVA)

| | Vascular Centres | | | | | | | | | | | |
|------------------------------|------------------|-----------------|------------------|-----------------|-----------------|------------------|-----------------|-----------------|-----------------|------------------|------------------|---------------------------------|
| | All | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | P value |
| Compression Therapy | 11.9 (24.9) | 24.1 (35.7) | 44.3 (44.3) | 6.3 (28.6) | 11.4 (9.7) | 16.9 (18) | 0.5 (3.1) | 2.0 (6) | 9.2 (21.1) | 11.3 (20.4) | 4.8 (8.2) | $F(9,622)=19.09$, $p<0.001$ |
| EWA | 27.6 (36.4) | 23.3 (34.2) | 49.3 (39.9) | 33.8 (38.6) | 30.9 (30.3) | 35.5 (44.6) | 14 (9.1) | 27 (38.6) | 14.9 (16.8) | 46.3 (42) | 33.4 (53.4) | $F(9,596)=6.59$, $p<0.001$ |
| Prosthetic Cast | 60.2 (57.5) | 64.1 (57.4) | 90.4 (66.6) | 72.8 (60.1) | 63.3 (51) | 62.5 (59) | 46.5 (39.3) | 47.6 (49.4) | 49.8 (46.8) | 76.1 (60) | 64.6 (79.2) | $F(9,633)=3.68$, $p<0.001$ |
| Prosthetic Delivery | 73.8 (59.8) | 82.8 (65.3) | 113.2 (75.4) | 79.6 (60.8) | 74.1 (51.1) | 74.8 (58.5) | 47.5 (39.4) | 56.9 (52.6) | 65.3 (55.6) | 90.4 (60.2) | 80.4 (61.2) | $F(9,633)=5.49$, $p<0.001$ |
| In-patient discharge | 67.6 (54.8) | 81.3 (43) | 66.6 (65) | 102.6 (60.7) | 103.9 (56.9) | 67.3 (41.4) | 66.7 (42.2) | 79.9 (49.7) | 52.1 (54) | 58.1 (57) | 32.7 (26.9) | $F(9,626)=12.21$, $p<0.001$ |
| Out-patient discharge | 166.1 (100.6) | 149.7 (95.5) | 240.1 (104.3) | 135.8 (68.3) | 134.7 (65.4) | 196.3 (144.7) | 100.1 (58.2) | 127.3 (82.7) | 186.4 (98.5) | 174.3 (114.8) | 210.9 (100.6) | $F(9,594)=10.91$, $p<0.001$ |